

5526 B17

MEMORANDUM/FAX

To: Mr. Baba Chitniss
Glaxo Inc.
Zebulon

25 July 1985

Zantac Syrup

As a result of a recent in-use test on Zantac Syrup in which we found there was a significant loss of propylparaben due to microbial contamination, the development programme of this syrup has been delayed pending further investigation.

A document was prepared for discussion at the International Standards Committee on 15 July 1985 but was withdrawn when the results of the in-use test became available.

In reply to your questions of 23 July, I am attaching relevant pages 4, 13, 14, 15, 16, 17, 34, 35, 107, 108 and 109 from the ISC discussion document. In order to estimate the number of creamer packs required for a stability tests, please refer to pages 107 and 108.

Test point X requires 2 x 10ml for tests (i)-(iv) and 2 x 10ml for test (v)
Test point Y requires 2 x 10ml for tests (i)-(ii) and 2 x 10ml for test (iii)

Please contact me if you have any further queries.

Regards.

David Long

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